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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/205,926	03/11/99	DALES J	P30520

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EXAMINER	
PERCH,M	
ART UNIT	**PAPER NUMBER**
1624	11

DATE MAILED: 08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/265,926	Applicant(s) Dales
	Examiner Mark L. Berch	Group Art Unit 1624

☒ Responsive to communication(s) filed on *Jul 27, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *5-7 and 10-14* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *5-7 and 10-14* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

The request filed on 7/27/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/265926 is acceptable and a CPA has been established. An action on the CPA follows.

In view of the Example 3b process, the description rejection is dropped.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 302,644.

Note Formula I. R_3 as amino is clearly preferred, as it is the sole choice seen in the final product. As for R_1, two choices are given as preferred at page 7, line 7, viz, methyl and ethyl. Claim 5 has the methyl. For R_2, there is a list on page 7, lines 8-9, which has 3 or 6 items in it, depending on how one counts, one of which is chloro. Thus, by using the explicitly set forth preferred choices for the variables, a Markush of 2 x 3 = 6 or 2 x 6 = 12 (depending again on how the list on page 7, lines 8-9 is counted) is present. A Markush group of either size is deemed to be an anticipation of

all 6 or 12. Note *In re Petering*, 133 USPQ 275; *In re Sivaramarishnan*, 213 USPQ 441 (which had a Markush group of around 70); *In re Schaumann*, 197 USPQ 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 -7 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 302,644.

The reasons were given previously; the traverse on this point is unpersuasive.

The declaration has four major flaws.

First, it does not properly replicate the prior art process for Stage 1, step 3, the decarboxylation of the triester, and second, it provides a version of the claimed process which does not fall within claim 10. In EP 302,644, the process is set forth in Example 3, i.e. the conversion of D12 (prepared in Description 12) to E3. This process appears as Step 3 on page 5 of the declaration, as is described on page 6, beginning on line 3. There are three significant differences:

A. EP 302,644 uses NaOEt in ethanol; the declaration uses NaOMe in methanol. Thus, not only is a different reagent used for the decarboxylation itself, but a transesterification is also being done. Note that in the reference, the conversion of D12 to E3 is <u>not</u> a transesterification, as one goes from the ethyl ester of D12 to the

ethyl ester of E3. Further, note that the claims do not require a transesterification either and indeed make no mention of transesterification, as they simply call the process a decarboxylation. As a result, the process as set forth in the declaration does not even fall within claim 10. Thus, a proper comparison in the declaration would have used NaOEt in ethanol in both the EP 302,644 and the claimed process.

B. EP 302,644 acidifies the mixture to pH 3 prior to solvent evaporation. The declaration process has no such step.

C. EP 302,644 purified the material, including a drying process, which converted the yellow oil to a crystalline solid. No such process occurs in the declaration.

Third, the reduction (stage 2, step 1) in the EP 302,644 process was done differently from what appears in the actual reference on page 18, step a). (The examiner assumes that the "6-Chloro" at the sixth from last line of page 6 of the declaration is a typographical error).

D. In EP 302,644, the reduction is done in t-butanol; in the declaration, in methylenedichloride.

E. In EP 302,644, the reduction is done at reflux; in the declaration it is done at 20 °C.

F. In EP 302,644, the methanol addition was done without chilling; in the declaration, the reaction mixture was chilled to keep it at room temperature.

G. In EP 302,644, the product is purified by chromatography before the acetylation; this step does not occur in the declaration. This is potentially important because the product is described in EP 302,644 as being a white solid, whereas in the declaration

it is described as being yellow colored. This means that it is likely that the EP 302,644 process produced a purer product than the declaration process, vitiating the comparison.

Fourth, the acetylation of the diol (stage 2, step 2) in the EP 302,644 process was done differently than what actually appears in the reference on page 19, step c): H. In EP 302,644, there was used THF as solvent alone with pyridine. In the declaration, there was used methylenedichloride as solvent plus triethylamine.
I. The workup was completely different. For example, in EP 302,644 there was a drying process and column chromatography; neither was seen in the declaration.

As a result of all these differences, applicants cannot be considered to have done a proper replication of the reference. It must be noted that the EP 302,644 reference starts where the declaration starts, and ends with the same diacetylated diol, yet applicants ended with a brown oil which they were unable to crystallize from n-butanol, whereas the EP 302,644 reference states that they were able to obtain colorless crystals from n-butanol, melting at 102 °C. It seems clear that these variations prevented a proper obtention of the results seen in EP 302,644. The conclusion that the prior art process yields only a useless brown oil is directly contradicted by the fact that the EP 302,644 did in fact produce the compound as colorless crystals of the correct melting point.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718.

Mark L. Berch

Primary Examiner

Group 1610 - Art Unit 1624

August 14, 2000